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PPLICATION NO.	FILI	NG DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/646,244	08/22/2003		Gust H. Bardy	020.0338.US.CON	9403
22895	7590	10/19/2004	•	EXAMINER	
PATRICK J	S INOUY	EPS	LAYNO, CARL HERNANDZ		
810 3RD AV	ENUE		,		
SUITE 258				ART UNIT	PAPER NUMBER
SEATTLE, WA 98104				3762	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)
Office Action Commons	10/646,244	BARDY, GUST H.
Office Action Summary	Examiner Can l H. Layno Carl H. Layno (a)(1) /04	Art Unit 3762
The MAILING DATE of this communication app		correspondence address
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPL' THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.1: after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statule Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be tir y within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONE	nely filed  /s will be considered timely. In the mailing date of this communication.  ID (35 U.S.C. § 133).
Status	•	•
1) ☐ Responsive to communication(s) filed on 22 A     2a) ☐ This action is FINAL. 2b) ☐ This     3) ☐ Since this application is in condition for alloware closed in accordance with the practice under E	action is non-final.  nce except for formal matters, pro	
Disposition of Claims		
4) ☐ Claim(s) 1-34 is/are pending in the application. 4a) Of the above claim(s) is/are withdray. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1,11-14,23-26,33 and 34 is/are reject. 7) ☐ Claim(s) 2-10,15-22 and 27-32 is/are objected. 8) ☐ Claim(s) are subject to restriction and/o. Application Papers 9) ☐ The specification is objected to by the Examine.	wn from consideration. red. to. or election requirement.	
10) ☐ The drawing(s) filed on 22 August 2003 is/are:  Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) ☐ The oath or declaration is objected to by the Explanation is objected.	drawing(s) be held in abeyance. Se tion is required if the drawing(s) is ob	e 37 CFR 1.85(a). ojected to. See 37 CFR 1.121(d).
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document application from the International Bureau * See the attached detailed Office action for a list	s have been received. Is have been received in Applicat rity documents have been receiv u (PCT Rule 17.2(a)).	ion No ed in this National Stage
Attachment(s)  1) ☑ Notice of References Cited (PTO-892)  2) ☑ Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) ☑ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>various</u> .	4)  Interview Summary Paper No(s)/Mail D 5)  Notice of Informal I 6)  Other:	

#### **DETAILED ACTION**

## **Priority**

1. Acknowledgment is made of applicant's claim for priority as a Continuation of U.S. Application Serial No.09/860,987, filed May 18, 2001, which is a continuation of U.S. Patent No. 6,280,380, which is a Continuation-In-Part of U.S Patent No. 6,221,011, filed on July 26, 1999.

## Information Disclosure Statement

2. Acknowledgment is made of applicant's Information Disclosure Statements (PTO-1449) which were received by the Office on August 22, 2003, September 26, 2003, December 15, 2003, March 18, 2004, April 30, 2004, and August 2, 2004.

#### **Drawings**

3. Applicant's formal drawings were received by the Office on August 22, 2003 have been approved by the Examiner.

### Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1, 13, 14, 25, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Walker et al '844.

The Walker et al '844 patent describes a system for patient care delivery (Fig. 1) comprising a plurality of medical devices 120 for obtaining physiological data from patients and transmitting this data to a central server 200 (col.4, lines 14-23). The server 200 includes a patient database 600 for storing patient medical histories, a database for storing physiological events 700 (Fig. 7), and a reaction database 300 for storing treatments for these events (Fig. 3). The system creates and stores baseline profiles for individual patients over a period of time (col.4, lines 1-6) and updates these profiles periodically (col.13, lines 11-13).

In regard to claims 13 and 25, the Walker et al system identifies and stores ventricular fibrillation events R31 (Fig.3); hence, "ventricular electrical activity" is one of the "reference measures" used.

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In regard to claim 26, the server 200 includes software code 1200 (Fig. 2) for activating the system of claim 1 and performing the method of claim 14. This software is stored in readable medium 250 (Fig. 2), which is accessible by a processor 220.

6. Claims 1, 11-14, 23-26, 33, and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Finkelstein et al '923.

The Finkelstein et al '923 patent describes a system and method for remotely monitoring asthma severity (Fig.2) comprising a medical device 120 having a spirometer 124 for measuring a patient's respiratory capacity. The device 120 includes transmission circuits 130 for facilitating wireless or landline communications over a network to a server 172 connected to a plurality of databases 174,176,178. In use, the Finkelstein et al system uses the spirometer 124 to measure 29 different patient respiratory parameters from forced vitality capacity (FVC) tests (See Fig.3). These FVC parameters are considered applicant's physiological "measured sets". These test results are recorded 450 in memory (Fig.4) and displayed to evaluating physicians 470 (Fig.4) using a graphical user interface (GUI) 300 (Fig.3). The graphical user interface displays test results 320 with recent results superimposed over baseline results (col.8, lines 11-14), and with data in tabular form with baseline predicted results 333 versus actual measured results 334, the difference in percentages 338 (col.8, lines 52-53).

In regard to claims 11, 23, and 33, the system of Finkelstein et al includes a diagnosis/evaluation station 180, which performs the function of applicant's "analysis module".

A physician at this station 180 compares previous data with new data graphically using

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superimposition of FVC curves to generate messages regarding a patient's respiratory status (col.7, lines 21-36).

In regard to claims 12, 24, and 34, GUI interface 300 (Fig.3) permits the physician to also view comparisons between baseline and present values of any one of 29 FVC parameters to help further assess a patient's status.

In regard to claims 13 and 25, the "reference measures" of Finkelstein et al are "pulmonary measures".

## Allowable Subject Matter

Claims 2-10, 15-22, and 27-32 are objected to as being dependent upon a rejected base 7. claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the 8. examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every other Friday between 9AM and 5PM. A voice mail or E-mail message (carl.layno@uspto.gov) may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (703) 308-5181. All faxed communications should be sent to the Office's Official FAX number (703) 872-9303.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (703) 305-7520.

CARL LAYNO
PRIMARY EXAMINER

Carl H. Layro

CHL 10/18/2004